Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-F55578D4-AFD0-45BB-9450-F4102CED4D18_3_en-US
DOI: https://doi.org/10.31003/USPNF_M17755_03_01
DOI Ref: eu9cx

Cimetidine in Sodium Chloride Injection

DEFINITION

Cimetidine in Sodium Chloride Injection is a sterile solution of Cimetidine Hydrochloride and Sodium Chloride in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of cimetidine ($C_{10}H_{16}N_6S$) and NLT 95.0% and NMT 110.0% of the labeled amount of sodium chloride (NaCl).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** **Identification Tests—General, *Sodium*⟨191⟩ and *Chloride*⟨191⟩:** Meets the requirements

ASSAY

- **Cimetidine**

Mobile phase: Transfer 200 mL of methanol and 0.3 mL of phosphoric acid to a 1000-mL volumetric flask, dilute with water to volume, and filter.

Standard stock solution: 0.5 mg/mL of USP Cimetidine Hydrochloride RS in a mixture of methanol and water (1:4)

Standard solution: 12.5 µg/mL of USP Cimetidine Hydrochloride RS in *Mobile phase* from *Standard stock solution*

Sample solution: Nominally 10.0 µg/mL of cimetidine, prepared as follows. Transfer an accurately measured volume of Injection, equivalent to about 2 mg of cimetidine, to a 200-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, *k'*: NLT 0.6

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cimetidine ($C_{10}H_{16}N_6S$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Cimetidine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of cimetidine in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of cimetidine, 252.34

M_{r2} = molecular weight of cimetidine hydrochloride, 288.81

Acceptance criteria: 90.0%–110.0%

• **Sodium Chloride**

Sample solution: Dilute a volume of Injection with water to obtain a solution containing 0.5 mg/mL of sodium chloride.

Analysis: Determine the total amount of chloride, *A*, in the *Sample solution*, in mg, by titrating the *Sample solution* with 0.1 N silver nitrate VS, using a silver–silver chloride electrode. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride.

To correct for the chloride present as cimetidine hydrochloride, calculate the concentration of chloride, *C*, due to sodium chloride, in mg/mL, in the *Sample solution*:

$$\text{Result} = (A/V) - [W \times (M_{Cl}/M_{r1})]$$

A = total amount of chloride in the *Sample solution* (mg)

V = volume of the Injection taken to prepare the *Sample solution* (mL)

W = quantity of cimetidine in the Injection, as determined in the *Assay* for *Cimetidine* (mg/mL)

M_{Cl} = atomic weight of chloride, 35.453

M_{r1} = molecular weight of cimetidine, 252.34

Calculate the percentage of the labeled amount of sodium chloride (NaCl) in the portion of Injection taken:

$$\text{Result} = (C/C_U) \times (M_{NaCl}/M_{Cl}) \times 100$$

C = concentration of chloride due to sodium chloride in the *Sample solution* (mg/mL)

C_U = nominal concentration of sodium chloride in the *Sample solution* (mg/mL)

M_{NaCl} = molecular weight of sodium chloride, 58.443

M_{Cl} = atomic weight of chloride, 35.453

Acceptance criteria: 95.0%–110.0%

SPECIFIC TESTS

• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 0.5 USP Endotoxin Unit/mg of cimetidine hydrochloride

• **pH** ⟨791⟩**:** 5.0–7.0

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

• **USP Reference Standards** ⟨11⟩

USP Cimetidine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CIMETIDINE IN SODIUM CHLORIDE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-F55578D4-AFD0-45BB-9450-F4102CED4D18_3_en-US
Previous DocID: GUID-F55578D4-AFD0-45BB-9450-F4102CED4D18_1_en-US
DOI: https://doi.org/10.31003/USPNF_M17755_03_01
DOI ref: eu9cx